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Substitute for form 1449B/PTO  
**INFORMATION DISCLOSURE  
 STATEMENT BY APPLICANT**

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**Complete if Known**

Application Number	10/661,402
Filing Date	09/12/2003
First Named Inventor	Andrew Vaillant
Group Art Unit	1814-1648
Examiner Name	Sharon Kent
Attorney Docket Number	029849-0207

**U.S. PATENT DOCUMENTS**

[illegible]

## FOREIGN PATENT DOCUMENTS

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## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
SN	A2	AGRAWAL and KANDIMALLA, "Antisense and/or Immunostimulatory Oligonucleotide Therapeutics," <i>Current Cancer Drug Targets</i> 1:197-209 (2001)	
SN	A3	ALLEN and CHONN, "Large Unilamellar Liposomes with Low Uptake into the Reticuloendothelial System," <i>FEBS Letters</i> 223(1):42-46 (1987)	
SN	A4	ARCHAMBAULT, <i>et al.</i> , "Phosphorothioate oligonucleotides inhibit the replication of lentiviruses and type D retroviruses, but not that of type C retroviruses," <i>Arch Virol</i> 139:97-109 (1994)	

**Examiner  
Signature**

Sharon Hurt

Date Considered

2-17-2006

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Sheet	2	of	13	Attorney Docket Number	029849-0207

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SH	A5	BERKOW, et al., "Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)," <i>The Merck Manual of Diagnosis and Therapy</i> , 15 <sup>th</sup> ed., 2499-2506 and 46-49 (1987)	
SH	A6	BLUME and CEVC, "Liposomes for the sustained drug release in vivo," <i>Biochimica et Biophysica Acta</i> 1029:91-97 (1990)	
SH	A7	BRUNTON, "Section VI Drugs Affecting Gastrointestinal Function," <i>The Pharmacological Basis of Therapeutics</i> 9(38):934-935 (1996)	
SH	A8	BUUR, et al., "Penetration of 5-Fluorouracil and Prodrugs Across the Intestine of the Albino Rabbit: Evidence for Shift in Absorption Site from the Upper to the Lower Region of the Gastrointestinal Tract by Prodrugs," <i>Journ. of Controlled Release</i> 14:43-51 (1990)	
SH	A9	CAMPBELL and REIN, "In Vitro Assembly Properties of Human Immunodeficiency Virus Type 1 Gag Protein Lacking the p6 Domain," <i>Journ. of Virol.</i> 73:2270-2279 (1999)	
SH	A10	CEVC, et al., "Ultraflexible vesicles, Transfersomes, have an extremely low pore penetration resistance and transport therapeutic amounts of insulin across the intact mammalian skin," <i>Biochimica et Biophysica Acta</i> 1368:201-215 (1998)	
SH	A11	CHENG, et al., "Interactions Between Single-Stranded DNA Binding Protein and Oligonucleotide Analogs with Different Backbone Chemistries," <i>Journ. Mol. Recognition</i> 10:101-107 (1997)	
SH	A12	CONSTANTINIDES, et al., "Formulation and Intestinal Absorption Enhancement Evaluation of Water-in-Oil Microemulsions Incorporating Medium-Chain Glycerides," <i>Pharmaceutical Res.</i> 11:1385-1390 (1994)	
SH	A13	CROOKE, et al., "Pharmacokinetic Properties of Several Novel Oligonucleotide Analogs in mice," <i>Journ. Pharm. and Experim. Therap.</i> 277(2):923-937 (1996)	
SH	A14	CROOKE, S., "Progress in Antisense Technology: The End of the Beginning," <i>Meth. in Enzym.</i> 313:3-45 (1999)	

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SH	A15	Du PLESSIS, <i>et al.</i> , "Topical Delivery of Liposomally Encapsulated Gamma-Interferon," <i>Antivir. Res.</i> 18:259-265 (1992)	
SH	A16	EL-HARIRI, <i>et al.</i> , "The Mitigating Effects of Phosphatidylcholines on Bile Salt- and Lysophosphatidylcholine-induced Membrane Damage," <i>J. Pharm. Pharmacol.</i> 44:651-654 (1992)	
SH	A17	ENGLISH and GAUSS, "Chemically Modified Oligonucleotides as Probes and Inhibitors," <i>Angewandte Chemie</i> 30(6):613-722 (1991)	
SH	A18	FENG, <i>et al.</i> , "Reversible Binding of Recombinant Human Immunodeficiency Virus Type 1 Gag Protein to Nucleic Acids in Virus-Like Particle Assembly In Vitro," <i>Journ. of Virol.</i> 76(22):11757-11762 (2002)	
SH	A19	FENNEWALD, <i>et al.</i> , "Inhibition of herpes simplex virus in culture by oligonucleotides composed entirely of deoxyguanosine and thymidine," <i>Antiviral Res.</i> 26:37-54 (1995)	
SH	A20	GABIZON, <i>et al.</i> , "Liposome formulations with prolonged circulation time in blood and enhanced uptake by tumors," <i>Proc. Natl. Acad. Sci. USA</i> 85:6949-6953 (1988)	
SH	A21	GOA, <i>et al.</i> , "Effect of Phosphorothioate Homo-oligodeoxynucleotides on Herpes Simplex Virus Type 2-induced DNA Polymerase," <i>Journ. of Biol. Chem.</i> 264(19):11521-11526 (1989)	
SH	A22	GAO, <i>et al.</i> , "Inhibition of Herpes Simplex Virus Type 2 Growth by Phosphorothioate Oligodeoxynucleotides," <i>Antimicrobial Agents and Chemotherapy</i> 34(5):808-812 (1990)	

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SH	A23	HIGUCHI, <i>et al.</i> , "Particle Phenomena and Course Dispersions," <i>Remington's Pharmaceutical Sciences</i> 21:301-329 (1985)	
SH	A24	HO, <i>et al.</i> , "Preparation of Microemulsions Using Polyglycerol Fatty Acid Esters as Surfactant for the Delivery of Protein Drugs," <i>Journ. of Pharm. Sci.</i> 85:138-143 (1996)	
SH	A25	HU, <i>et al.</i> , "Topical delivery of cyclosporine A from non-ionic liposomal systems: an <i>in vivo/in vitro</i> correlation study using hairless mouse skin," <i>S.T.P. Pharma Sciences</i> 4(6):466-469 (1994)	
SH	A26	ILLUM and DAVIS, "The organ uptake of intravenously administered colloidal particles can be altered using a non-ionic surfactant (Poloxamer 338)," <i>FEBS</i> 1212 167:79-82 (1984)	
SH	A27	INAGAWA, <i>et al.</i> , "Inhibition of human immunodeficiency virus type 1 replication by P-stereodefined oligo (nucleoside phosphorothioate)s in a long-term infection model," <i>FEBS Lett.</i> 528:48-52 (2002)	
SH	A28	JAIRATH, <i>et al.</i> , "Inhibition of respiratory syncytial virus replication by antisense oligodeoxyribonucleotides," <i>Antiviral Res.</i> 33:201-213 (1997)	
SH	A29	JARRETT, H., "Affinity chromatography with nucleic acid polymers," <i>J. Chromotography</i> 618:315-339 (1993)	
SH	A30	KABANOV, <i>et al.</i> , "A new class of antivirals: antisense oligonucleotides combined with a hydrophobic substituent effectively inhibit influenza virus reproduction and synthesis of virus-specific proteins in MDCK cells," <i>FEBS Lett.</i> 259:327-330 (1990)	

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SH	A31	KANDIMALLA, <i>et al.</i> , "Effects of Phosphorothioate Oligodeoxyribonucleotide and Oligoribonucleotides on Human Complement and Coagulation," <i>Bioorg. &amp; Med. Chem. Lett.</i> 8:2103-2108 (1998)	
SH	A32	KEAN, <i>et al.</i> , "Inhibition of Herpes Simplex Virus Replication by Antisense Oligo-2'-O-methylribonucleoside Methylphosphonates," <i>Biochemistry</i> 34:14617-14620 (1995)	
SH	A33	KLIBANOV, <i>et al.</i> , "Amphipathic polyethyleneglycols effectively prolong the circulation time of liposomes," <i>FEBS Lett.</i> 268:235-237 (1990)	
SH	A34	KLIMUK, <i>et al.</i> , "Enhanced Anti-Inflammatory Activity of a Liposomal Intercellular Adhesion Molecule-1 Antisense Oligodeoxynucleotide in an Acute Model of Contact Hypersensitivity," <i>Jour. of Pharm. &amp; Exper. Ther.</i> 292:480-488 (2000)	
SH	A35	KOOL, E., "Replacing the Nucleobases in DNA with Designer Molecules," <i>Acc. Chem. Res.</i> 35:936-943 (2002)	
SH	A36	LAVIGNE <i>et al.</i> , "Is antisense an appropriate nomenclature of design for oligodeoxynucleotides aimed at the inhibition of HIV-1 replication?" <i>AAPS PharmSci</i> , 4:1-11, 2002	
SH	A37	LEBEDEVA and STEIN, "Antisense Oligonucleotides: Promise and Reality," <i>Annu. Rev. Pharmacol. Toxicol.</i> 41:403-419 (2001)	
SH	A38	LEE, <i>et al.</i> , "Mucosal Penetration Enhancers For Facilitation of Peptide and Protein Drug Absorption," <i>Crit. Rev. in Ther. Drug Carrier Syst.</i> 8(2):91-192 (1991)	

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SH	A39	LERNER, <i>et al.</i> , "A Six-Month Trial of Valacyclovir in the Epstein-Barr Virus Subset of Chronic Fatigue Syndrome: Improvement in Left Ventricular Function," <i>Drugs of Today</i> 38(8): 549-561 (2002)	
SH	A40	LETSINGER, <i>et al.</i> , "Cholesteryl-conjugated oligonucleotides: Synthesis, properties, and activity as inhibitors of replication of human immunodeficiency virus in cell culture," <i>Proc. Natl. Acad. Sci. USA</i> 86:6553-6556 (1989)	
SH	A41	MANOHARAN, <i>et al.</i> , "Chemical Modifications to Improve Uptake and Bioavailability of Antisense Oligonucleotides," <i>Ann. N.Y. Acad. Sci.</i> 660:306-309 (1992)	
SH	A42	MANOHARAN, <i>et al.</i> , "Introduction of a Lipophilic Thioether Tether in the Minor Groove of Nucleic Acids for Antisense Applications," <i>Bioorg. &amp; Med. Chem. Letters</i> 3:2765-2770 (1993)	
SH	A43	MANOHARAN, <i>et al.</i> , "Cholic Acid-Oligonucleotide Conjugates for Antisense Applications," <i>Bioorg. &amp; Med. Chem. Lett.</i> 4:1053-1060 (1994)	
SH	A44	MANOHARAN, <i>et al.</i> , "Oligonucleotide Conjugates: Alteration of the Pharmacokinetic Properties of Antisense Agents," <i>Nucleosides &amp; Nucleotides</i> 14(3-5):969-973 (1995)	
SH	A45	MANOHARAN, <i>et al.</i> , "Lipidic Nucleic Acids," <i>Tetrahedron Lett.</i> 36:3651-3654 (1995)	
SH	A46	MARHSALL, <i>et al.</i> , "Inhibition of human immunodeficiency virus activity by phosphorodithioate oligodeoxycytidine," <i>Proc. Natl. Acad. Sci. USA</i> 89:6265-6269 (1992)	

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SH	A47	MARSHALL and CARUTHERS, "Phosphorodithioate DNA as a Potential Therapeutic Drug," <i>Science</i> 259:1564-1570 (1993)	
SH	A48	MATSUKURA et al., "Antisense phosphorothioates as antivirals against human immunodeficiency virus (HIV) and hepatitis B virus (HBV)." <i>Toxicology Letters</i> , 82/83: 435-538, 1995.	
SH	A49	MATSUKURA, et al., "Phosphorothioate Analogs of Oligodeoxynucleotides: Inhibitors of Replication and Cytopathic Effects of Human Immunodeficiency Virus," <i>Proc. Natl. Acad. of Sciences of USA</i> 84:7706-7710 (1987)	
SH	A50	MISHRA, et al., "Improved leishmanicidal effect of phosphorothioate antisense oligonucleotides by LDL-mediated delivery," <i>Biochimica et Biophysica Acta</i> 1264:229-237 (1995)	
SH	A51	MIYANO-KUROSAKI et al., "Inhibition of HTLV-I induction and virus-induced syncytia formation by oligodeoxynucleotides." <i>Virus Genes</i> , 12:205-217, 1996.	
SH	A52	MIYAO, et al., "Stability and Pharmacokinetic Characteristics of Oligonucleotides Modified at Terminal Linkages in Mice," <i>Antisense Res. &amp; Dev.</i> 5:115-121 (1995)	
SH	A53	MONTEITH, et al., "Preclinical Evaluation of the Effects of a Novel Antisense Compound Targeting C-raf Kinase in Mice and Monkeys," <i>Toxicolog. Sciences</i> 46:365-375 (1998)	
SH	A54	MORRIS, et al., "High Affinity Ligands from <i>in vitro</i> Selection: Complex Targets," <i>Proc. Natl. Acad. Sci. USA</i> 95:2902-2907 (1998)	

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SH	A55	MURANISHI, S., "Absorption Enhancers," <i>Crit. Rev. in Ther. Drug Carr. Syst.</i> 7:1-33 (1990)	
SH	A56	NANDI, et al., "DNA-induced Partial Unfolding of Prion Protein Leads to its Polymerisation to Amyloid," <i>J. Mol. Biol.</i> 322:153-161 (2002)	
SH	A57	NEURATH, et al., "Anti-HIV-1 activity of anionic polymers: a comparative study of candidate microbicides," <i>BMC Infectious Diseases</i> 2:1-11 (2002)	
SH	A58	OBERHAUSER and WAGNER, "Effective incorporation of 2'-O-methyl-oligoribonucleotides into liposomes and enhanced cell association through modification with thiocholesterol," <i>Nucleic Acids Res.</i> 20(3):533-538 (1992)	
SH	A59	OLIVIERI, et al., "Hepatitis C Virus and Arthritis," <i>Rheumatic Diseases Clinics of North America</i> 29:1-18 (2003)	
SH	A60	ORUM and WENGEL, "Locked nucleic acids: A promising molecular family for gene-function analysis and antisense drug development," <i>Curr. Op. in Molecular Ther.</i> 3:239-243 (2001)	
SH	A61	PAN et al., "Isolation of virus-neutralizing RNAs from a large pool of random sequences." <i>Proc. Nat. Acad. Sci. USA</i> , 92:11509-11513, 1995.	
SH	A62	PAPAHADJOPOULOS, et al., "Targeting of Liposomes to Tumor Cells <i>in Vivo</i> ," <i>Ann. N.Y. Acad. Sci.</i> pp. 64-74 (1987)	

Examiner Signature	Sharon Huet	Date Considered	2-7-2006
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		Application Number	10/661,402
		Filing Date	09/12/2003
		First Named Inventor	Andrew Vaillant
		Group Art Unit	1614
		Examiner Name	
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SH	A63	PEYMAN, <i>et al.</i> , "Inhibition of Viral Growth by Antisense Oligonucleotides Directed against the IE110 and the UL30 mRNA of Herpes Simplex Virus Type-1," <i>Biol. Chem. Hoppe-Seyler</i> 376:195-198 (1995)	
SH	A64	QI, <i>et al.</i> , "Study on the inhibitory effect of antisense phosphorothioate oligodeoxynucleotide on coxsackie virus B <sub>3</sub> replication <i>in vitro</i> ," <i>Chinese J Exp. Clin. Virol.</i> 14:253-256 (2000)	
SH	A65	RITSCHER, W., "Standards of Clinical Investigations in the USA," <i>Meth. Find Exp. Clin. Pharmacol.</i> 15(4):207-215 (1993)	
SH	A66	SAISON-BEHMOARAS, <i>et al.</i> , "Short modified antisense oligonucleotides directed against Ha-ras point mutation induce selective cleavage of the mRNA and inhibit T24 cells proliferation," <i>The EMBO Journal</i> 10:1111-1118 (1991)	
SH	A67	SANGHVI, Y., "Heterocyclic Base Modifications in Nucleic Acids and Their Applications in Antisense Oligonucleotides," <i>Antisense Research and Applications</i> Ch. 15:273-288 (1993)	
SH	A68	SCHOTT, H., "Colloidal Dispersions," <i>Remington's Pharmaceutical Sciences</i> Ch. 20:271-300 (1985)	
SH	A69	SHEA, <i>et al.</i> , "Synthesis, hybridization properties and antiviral activity of lipid-oligodeoxynucleotide conjugates," <i>Nucleic Acids Res.</i> 18:3777-3783 (1990)	
SH	A70	STAHL, <i>et al.</i> , "High Incidence of Parvovirus B19 DNA in Synovial Tissue of Patients with Undifferentiated Mono- and Oligoarthritis," <i>Clin. Rheumatol.</i> 19:281-286 (2000)	

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SH	A71	STEIN and CHENG, "Antisense Oligonucleotides as Therapeutic Agents-Is the Bullet Really Magical?" <i>Science</i> 261:1004-1012 (1993)	
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SH	A73	STEIN, C.A., "The experimental use of antisense oligonucleotides: a guide for the perplexed," <i>J. Clin. Invest.</i> 108:641-644 (2001)	
SH	A74	SUNAMOTO, et al., "Liposome Membranes. V. Interaction of Zinc(II) Ion with Egg Phosphatidylcholine Liposomes," <i>Bull. Chem. Soc. Jpn.</i> 53:2778-2781 (1980)	
SH	A75	SWINYARD, <i>Remington's Pharmaceutical Sciences</i> 18th Ed., Ch. 39:782-783 (1990)	
SH	A76	SVINARCHUK, et al., "Inhibition of HIV proliferation in MT-4 cells by antisense oligonucleotide conjugated to lipophilic groups," <i>Biochimie</i> 75:49-54 (1993)	
SH	A77	TAKAHASHI and YAMADA, "Viral Etiology for Parkinson's Disease - A Possible Role of Influenza A Virus Infection," <i>Jpn J Infect Dis.</i> 52:89-98 (1999)	
SH	A78	TAKAHASHI, et al., "The Use of Perfluorochemical Emulsion as a Vascular Perfusate in Drug Absorption," <i>J. Pharm. Pharmacol</i> 40:252-257 (1988)	

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		First Named Inventor	Andrew Vaillant
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SH	A79	TAKAKURA, <i>et al.</i> , "Uptake Characteristics of Oligonucleotides in the Isolated Rat Liver Perfusion System," <i>Antisense &amp; Nucleic Acid Drug Developmt.</i> 6:177-183 (1996)	
SH	A80	TAKESHITA, <i>et al.</i> , "Oligodeoxynucleotides Containing Synthetic Abasic Sites," <i>Journ. of Biol. Chem.</i> 262:10171-10179 (1987)	
SH	A81	TALBOT, <i>et al.</i> , "Virus-Induced Autoimmune Reactions in the CNS," <i>Curr Top Microbiol Immunol</i> 253:247-271 (2001)	
SH	A82	KROSCWITZ, J. I., <i>The Concise Encyclopedia Of Polymer Science And Engineering</i> , pp. 858-864 (1990)	
SH	A83	<i>The Merck Manual of Diagnosis and Therapy</i> 15:1206-1228 (1987)	
SH	A84	TONKINSON, <i>et al.</i> , "Cellular Pharmacology and Protein Binding of Phosphoromonothioate and Phosphorodithioate Oligodeoxynucleotides: A Comparative Study," <i>Antisense Res. &amp; Developmt.</i> 4:269-278 (1994)	
SH	A85	VIVES, <i>et al.</i> , "Lipophilic pro-oligonucleotides are rapidly and efficiently internalized in HeLa cells," <i>Nucleic Acids Res.</i> 27:4071-4076 (1999)	
SH	A86	WALTER, <i>et al.</i> , "Viral induction of a chronic asthma phenotype and genetic segregation from the acute response," <i>Journ. of Clin. Invest.</i> 110:165-286 (2002)	

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SH	A87	WANG and HUANG, "Plasmid DNA Adsorbed to pH-Sensitive Liposomes Efficiently Transforms the Target Cells," <i>Bioch. &amp; Biophys. Res. Comm.</i> 147(3):980-985 (1987)	
SH	A88	WEINER, <i>et al.</i> , "Liposomes: A Novel Topical Delivery System for Pharmaceutical and Cosmetic Applications," <i>Journ. of Drug Targeting</i> 2:405-410 (1994)	
SH	A89	WU, <i>et al.</i> , "Increased Microvascular Permeability Contributes to Preferential Accumulation of Stealth Liposomes in Tumor Tissue," <i>Cancer Research</i> 53:3765-3770 (1993)	
SH	A90	YAMAMOTO, <i>et al.</i> , "A Mechanistic Study on Enhancement of Rectal Permeability to Insulin in the Albino Rabbit," <i>Journ. of Pharm. and Exp. Ther.</i> 263:25-31 (1992)	
SH	A91	YAMASHITA, <i>et al.</i> , "Effects of diclofenac sodium and disodium ethylenediaminetetraacetate on electrical parameters of the mucosal membrane and their relation to the permeability enhancing effects in the rat jejunum," <i>J. Pharm. Pharmacol.</i> 39:621-626 (1987)	
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SH	A93	YU, <i>et al.</i> , "Stereo-Enriched Phosphorothioate Oligodeoxynucleotides: Synthesis, Biophysical and Biological Properties," <i>Biorg. &amp; Medicinal Chem.</i> 8:275-284 (2000)	
SH	A94	ZAMECNIK, <i>et al.</i> , "Inhibition of replication and expression of human T-cell lymphotropic virus type III in cultured cells by exogenous synthetic oligonucleotides complementary to viral RNA," <i>Proc. Natl. Acad. Sci. USA</i> 83:4143-4146 (1986)	

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SA	A95	ZHOU and HUANG, "Targeted delivery of DNA by liposomes and polymers," <i>Journ. of Controlled Release</i> 19:269-274 (1992)	
SN	A96	International Search Report from PCT Application No. PCT/IB03/04573 dated Feb. 18, 2004.	

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